

§ 571.6

to be used, at any time while a petition is under consideration. The Commissioner shall specify in the request for a sample of the food additive, or articles used as components thereof, or of the food in or on which the additive is proposed to be used, a quantity deemed adequate to permit tests of analytical methods to determine quantities of the food additive present in foods for which it is intended to be used or adequate for any study or investigation reasonably required with respect to the safety of the food additive or the physical or technical effect it produces. The date used for computing the 90-day limit for the purposes of section 409(c)(2) of the act shall be moved forward 1 day for each day after the mailing date of the request taken by the petitioner to submit the sample. If the information or sample is requested a reasonable time in advance of the 180 days, but is not submitted within such 180 days after filing of the petition, the petition will be considered withdrawn without prejudice.

(k) If nonclinical laboratory studies are involved, petitions filed with the Commissioner under section 409(b) of the act shall include, with respect to each study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

[41 FR 38647, Sept. 10, 1976, as amended at 42 FR 15675, Mar. 22, 1977; 50 FR 7518, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985; 52 FR 8583, Mar. 19, 1987; 57 FR 6476, Feb. 25, 1992; 62 FR 40600, July 29, 1997]

§ 571.6 Amendment of petition.

After a petition has been filed, the petitioner may submit additional information or data in support thereof. In such cases, if the Commissioner determines that the additional information or data amounts to a substantive amendment, the petition as amended will be given a new filing date, and the time limitation will begin to run anew. If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions shall include, with respect to each such study, either a statement

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that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason or the noncompliance.

[41 FR 38647, Sept. 10, 1976, as amended at 50 FR 7518, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985]

§ 571.7 Withdrawal of petition without prejudice.

(a) In some cases the Commissioner will notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a regulation or the regulation requested by petitioner. This may be due to the fact that the data are not sufficiently clear or complete. In such cases, the petitioner may withdraw the petition pending its clarification or the obtaining of additional data. This withdrawal will be without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew from the date of refiling.

(b) At any time before the order provided for in § 571.100(a) has been forwarded to the FEDERAL REGISTER for publication, the petitioner may withdraw the petition without prejudice to a future filing. Upon refiling the time limitation will begin to run anew.

Subpart B—Administrative Actions on Applications

§ 571.100 Regulation based on petition.

(a) The Commissioner will forward for publication in the FEDERAL REGISTER, within 90 days after filing of the petition (or within 180 days if the time is extended as provided for in section 409(c)(2) of the act), a regulation prescribing the conditions under which the food additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity that may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure